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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,970	07/17/2003	Roney Graf	33333/US	2032

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EXAMINER	
HAN, MARK K	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,970	GRAF ET AL.	
	Examiner	Art Unit	
	Mark K. Han	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-13, 18 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,086,567 in view of U.S. Patent No. 4,936,833 to Sams (hereinafter "Sams '833").

The application claims contain limitations that are either expressly or inherently disclosed in the patented claims. The patented claims, however, do not show a casing having a transparent area. Sams '833 shows a casing 7 with a transparent window 8. See Figures 1-15. It would have been obvious to one of ordinary skill in the art to include a casing with a transparent window of Sams '833 in the claim limitations of the '567 patent in order to protect the dosage scale from being worn down.

2. Claims 14 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,086,567 in view of Sams '833, further in view of U.S. Patent No. 4,865,591 to Sams (hereinafter "Sams '591").

The patented claims and Sams '833 disclose the claimed invention as shown above except for a marking line. Sams '591 discloses a marking line 9. See Figure 1. It would have been obvious to one of ordinary skill in the art to modify the invention of the patented claims and Sams '833 by including a marking line, as suggested by Sams, '591, in order to accurately provide a dosage.

3. Claims 16 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,086,567 in view of Sams '833, further in view of U.S. Patent No, 5,728,074 to Castellano et al. (hereinafter "Castellano").

In reference to claim 16, the limitations are shown above except for a cannula less than a 30 gauge. Castellano discusses the use of a 27-gauge needle. See col. 7, lines 52-54. It would have been obvious to one of ordinary skill in the art to modify the invention of the '567 patent and Sams '833 by including a 27-gauge needle to achieve optimum results

In reference to claim 17, the '567 patent, Sams '833 and Castellano disclose the claimed limitation as shown above. The '567 patent, Sams '833 and Castellano, however, do not disclose expressly using a 31 or 32-gauge cannula. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a 31 or 32-gauge cannula instead of a 27-gauge cannula because Applicant has not disclosed that a 31 or 32-gauge cannula provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with 27-gauge cannula because both provide a means to deliver medication. The choice of the cannula gauge is dependent on the location of the injection. Therefore, it

would have been an obvious matter of design choice to modify the '567 patent, Sams '833 and Castellano to obtain the invention as specified in claim 17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-13, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sams '833.

Sams '833 shows a casing 102, reservoir 100, driven device 5, dosing means 9, dosage scale 9, drive device 30, delivery stopper 20, transparent area 8, a second indicator 10, inner dosing body 65, outer dosing body 120, dosing member 64, piston 108 and piston rod 22. See Figures 1-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sams '833 to Sams '591.

Sams '833 discloses the claimed invention as shown above except for a marking line. Sams '591 discloses a marking line 9. See Figure 1. It would have been obvious to one of ordinary skill in the art to modify the invention of Sams '833 by including a marking line, as suggested by Sams, '591, in order to accurately provide a dosage.

6. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sams '833 in view of Castellano.

In reference to claim 16, the limitations are shown above except for a cannula less than a 30 gauge. Castellano discusses the use of a 27-gauge needle. See col. 7, lines 52-54. It would have been obvious to one of ordinary skill in the art to modify the invention of Sams '833 by including a 27-gauge needle, as suggested by Castellano, to achieve optimum results

In reference to claim 17, Sams '833 and Castellano disclose the claimed limitation as shown above. Sams '833 and Castellano, however, do not disclose expressly using a 31 or 32-gauge cannula. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a 31 or 32-gauge cannula instead of a 27-gauge cannula because Applicant has not disclosed that a 31 or 32-gauge cannula provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with 27-gauge cannula because both provide a means to deliver medication. The choice of the cannula gauge is dependent on the location of the injection. Therefore, it would have been an obvious matter of design choice to modify Sams '833 and Castellano to obtain the invention as specified in claim 17.

Response to Arguments

7. Applicant's arguments filed 09 May 2005 have been fully considered but they are not persuasive. Applicant argues that the limitation of a "drive device forms an indicator of the dosage scale, in order to indicate the initial position of the drive device in the transparent area of the casing, relative to said dosage marks.". Examiner disagrees. It is the Examiner's position that the drive device 30, which is coupled to the driven device, provides an indicator of the dosage scale either through the transparent area of the housing or by its general rearward axial movement caused by the setting of the dosage.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mkh.

Mark K. Han
Patent Examiner
Art Unit 3763

mkh
July 27, 2005

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